REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed June 12, 2008 ("Office Action"). Claims 1-47 pending. Claims 1,4, 8, 12, 14, 18, 23, 24, 29, 30, 34, 35, 39, and 40 are amended. Claims 44-47 are new. Support for the new and amended claims can be found in the specification, for instance, paragraphs 11, 12, 24, 42, 55, 56, etc. *See* Specification, as published, U.S. Patent Application Publication No. 2004/0185101 A1. Applicant respectfully requests reconsideration and allowance of the pending claims for the following reasons.

Anticipation -- 35 U.S.C. § 102

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Id.* However, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." Manual of Patent Examining Procedure § 2112 IV (citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art.). "In relying on a theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied prior art." M.P.E.P. § 2112 IV (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)).

The Office Action rejects the claims 1-43 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,004,573 ("Rathi").

Rathi discloses biodegradable low molecular weight triblock poly(lactide-co-glycolide) polyethylene glycol copolymers having reverse thermal gellation properties in aqueous solution at body temperature. The reverse thermal gellation property describes a compound that exists as a liquid solution at low temperatures and reversibly forms gels at physiologically relevant temperatures, to provide good drug release characteristics. Rathi, col. 4, ll. 56-61. The triblock copolymers of Rathi exist in the liquid state at low temperature, but upon parenteral

administration (*e.g.*, injection) into the body form a gel depot from which the drugs are released at a controlled rate. Fig. 1 shows that the transition to gel states occurs at a temperature of approximately 20°C (for compositions having 10 wt. % copolymer) to approximately 12°C (for compositions having 28 wt. % copolymer). The weight average molecular weight of the triblock copolymers disclosed by Rathi is between about 3100 and 4500 Daltons.

At the outset, the Office Action asserts that the claims include a functional polymer range of 1-50%. Office Action, page 5. Dependent claims 9, 14, 24, 30, 35, and 40 have been amended to replace the requirement for a functional concentration of 1 to 50% with a requirement that the block copolymer have a concentration that is between about 10 to 30% by weight which is consistent with the concentration in the range of about 5 to 40% as set forth in the independent claims. The pending independent claims require a block copolymer concentration in the range of about 5 to 40%. At such concentrations, Rathi exhibits reverse thermal gellation and therefore does not disclose every claim element as discussed in further detail below. The pending claims have also been amended to require a composition that "remains a free flowing liquid upon parenteral administration." Rathi does not disclose a composition that remains a free flowing liquid upon parenteral administration. Rathi describes a composition that forms a gel depot upon parenteral administration. Accordingly, the rejection of the pending claim under 35 U.S.C. § 103 as being obvious over Rathi must be withdrawn.

Applicant agrees that "[p]roducts of identical chemical composition can not have mutually exclusive properties." Indeed, "[f]rom the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." *In re Papesch*, 137 USPQ 43, 51 (C.C.P.A. 1963). The difference in the properties of the claimed compositions and the properties of Rathi prove that the compositions differ. The Office Action points to various instances where the claimed ranges approach, touch, or overlap, endpoints or points within the broadly disclosed ranges of Rathi. However, it is axiomatic that "the disclosure of a range is no more a disclosure of the end points of the range than it is of each of the intermediate points." *Atofina v. Great Lakes Chemical Corp.*, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006). None of the examples disclosed in Rathi include compositions which have the claimed properties. Indeed, all of the examples disclosed by Rathi exhibit reverse thermal gellation. The ranges pointed to by the Examiner are broad and involve numerous factors such as molecular weight, composition of the block copolymer, and concentration of the block copolymer. One would be required to

control each of these factors in a manner inconsistent with the purpose of Rathi in order to achieve the claimed invention. The claims now require a "polymeric composition [that] has a block copolymer concentration in the range of about 5 to 40%, and said polymeric composition when formed as an aqueous polymer solution, remains a free flowing liquid upon parenteral administration." Rathi fails to disclose each and every limitation of the claimed invention, either expressly or inherently. Therefore, rejection for anticipation by inherency based on Rathi is improper and must be withdrawn.

New claims 44 to 47 include, among other limitations, the requirement of about 52% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester. The data in the specification demonstrates that compositions having about 52% by weight of a biodegradable hydrophobic A polymer block exhibit the solubility enhancing effect over the ranges claimed. As shown in Example 1, the PEG 1000 results in a molecular weight for the block copolymer of 2324 as measured by GPC. The PLGA/PEG ratios in the table, coupled with the PEG Molecular weights of 600, 1000, and 1450 demonstrate that the "solubilizing enhancing function" is present over the molecular weight range of claims 44-47. As discussed above, "a compound and all of its properties are inseparable." Accordingly, claims 44-47 distinguish Rathi as they are directed to compositions which unexpectedly remain a free flowing liquid.

Obviousness-Type Double Patenting

The Office Action rejects claims 1-43 for obviousness-type double patenting over U.S. Patent No. 6,201,072. The claims of U.S. Patent No. 6,201,072 requires a polymer "possessing reverse thermal gellation properties." In contrast, the present claims require a composition that "remains a free flowing liquid upon parenteral administration." There is no overlap between the present claims and those of the '072 patent. Moreover, to the extent that one would modify the claimed invention of Rathi to achieve the presently claimed invention, such modification would render the polymer of Rathi unsuitable for its purpose as reflected in the '072 patent claims (i.e., reverse thermal gellation) which is an improper obviousness rationale. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984) ("Indeed, if the French apparatus were turned upside down, it would be rendered inoperable for its intended purpose . . . . In effect, French teaches away from the board's proposed modification."). Likewise, as discussed above, new claims 44-47 are directed to compositions which unexpected and distinct properties relative to the compositions disclosed